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20. A method for the treatment of muscle disuse syndrome in an animal or human for which such treatment is indicated, comprising administering a creatine compound in unit dosage form in an amount effective to treat said muscle disuse syndrome.--

REMARKS

Claims 19 and 20 have been added. Reexamination and reconsideration of the application, as amended, is requested.

Claims 9 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement. The Examiner states that the specification is enabling for the "treatment" of muscle disuse syndrome as described in claims 9 and 13, but does not enable one skilled in the art to practice the "prevention" of muscle disuse syndrome in accord with claims 9 and 13. Applicant respectfully traverses this rejection because it is predictable in the art reasonably to anticipate the onset of muscle disuse syndrome. The claimed invention can be preventive when the therapeutic preparation is administered to an individual from the onset of the risk to develop muscle disuse syndrome. For example, the syndrome occurs in skeletal muscle subject to reduced mechanical loading. Many conditions can result in reduced mechanical loading, such as forced bed rest, physical and/or mental handicap, sedentary lifestyle due to aging, or any other condition that results in a state of immobilization or reduced physical activity. At the onset of any one of these conditions, there is the accompanying directly foreseeable risk to develop muscle disuse syndrome. Thus, anticipation of the syndrome can be predicted and preventive treatment can be administered whenever reduced mechanical loading of a subject's skeletal musculature is observed. Furthermore, the Examiner states that undue,

unpredictable experimentation is required to practice the claimed invention. Applicant respectfully submits that the specification sets forth an appropriate dosage of the claimed creatine-based therapeutic preparation to administer in cases of muscle disuse syndrome on page 4, lines 8 through 14. In other words, those skilled in the art know from the specification: who has the syndrome; who predictably will encounter the syndrome; and how treat the syndrome with an active agent whose dosing recommendations are provided in the specification.

Claims 9-11, 13-14, and 16-17 stand rejected under 35 U.S.C. § 102(b) for purported anticipation by JP 08224073. Applicant respectfully traverses this rejection, because the JP patent teaches a creatine-based health, tonic or nutrition drink that can be given to individuals suffering from mere muscle fatigue after muscles have undergone physical strain. Such a teaching is in direct contrast to the claimed invention, which discloses the beneficial effect of the therapeutic preparation on immobilized muscles, not strained ones. The JP patent, therefore, does not teach or suggest a creatine-based therapeutic preparation for treating or preventing muscle disuse syndrome, or a method for treating or preventing muscle disuse syndrome in an animal or human, as set forth in independent claims 9 and 13, respectively.

Claims 9-11, 13-14, 16 and 18 stand rejected under 35 U.S.C. § 102(b) for asserted anticipation by XP-002101314 by Wyss et al. Applicant respectfully traverses this rejection on the basis that the cited article teaches an oral creatine supplement for alleviating muscle weakness and degeneration caused by muscle disease, specifically muscular dystrophy. Muscle disuse syndrome is related to muscular disease only in that muscular disease may be associated with reduced mechanical loading caused by any

muscle disease, aging, physical or mental handicap, forced bed rest, or any condition likely to reduce levels of physical activity. However, the therapeutic preparation and methods of the claimed invention are applied to the symptoms of muscle disuse. Muscle disuse syndrome does not lead to muscle cell death or irreversible destruction of cells as muscle disease states typically do. Also, muscle disuse syndrome characteristically relates to a decrease in cell volume and functional capacity only. The cited reference does not teach or suggest a therapeutic preparation for treating or preventing muscle disuse syndrome, or a method for treating or preventing muscle disuse syndrome in an animal or human, as claimed in independent claims 9 and 13, respectively.

Claims 9-11,13, and 15-18 stand rejected under 35 U.S.C. § 102(b) for asserted anticipation by European Patent Application No. 0222257 to Cannata et al. Applicant respectfully traverses this rejection, because the Cannata patent teaches a phosphocreatine composition for parenteral administration to treat pathological conditions of skeletal muscle, namely muscular atrophy and dystrophy. In contrast, the therapeutic preparation of the claimed invention is orally administered as a drug, nutritional supplement or foodstuff as described in dependent claims 11 and 12. Thus, by its very narrow teaching of a particular composition and parenteral administration, the Cannata reference does not teach or suggest any of the pending claims.

Claims 9-11 stand rejected under 35 U.S.C. § 102(b) for asserted anticipation by United States Patent No. 5,627,172 to Almada et al. Applicant respectfully traverses this rejection on the basis that the Almada patent teaches the use of creatine or creatine derivatives in tablets, powders or candy bars as a method to lower serum lipid or lipid components. In addition, the Almada patent discloses prior art which

teaches various applications for administering creatine or creatine derivatives, namely as ergogenic aids, to increase muscular performance, as a treatment for gyrate atrophy of the choroid and retina, as a treatment for muscular dystrophy, and for cardiac functional impairment. Ergogenic aids are typically taken by healthy athletes in order to improve muscle performance during short maximal exercise bouts. In contrast, the therapeutic preparation and methods therefor of the claimed invention are applied to individuals, in order to retain optimal performance of skeletal muscle, that may present, or are currently presenting with symptoms of muscle disuse, rather than individuals performing muscle activity or suffering from muscular disease.

Claims 12-18 stand rejected under 35 U.S.C. § 103(a) for asserted obviousness by United States Patent No. 5,627,172 to Almada et al. in view of the references cited therein. Applicant respectfully traverses this rejection on the basis that the Almada patent teaches the use of creatine or creative derivatives in tablets, powders or candy bars as a method to lower serum lipid or lipid components, and it would not be obvious to one of ordinary skill in the art at the time the invention was made to use Almada's composition to treat muscle disuse syndrome. Furthermore, Applicant respectfully reiterates that the prior art disclosures in the Almada patent teach various applications for administering creatine or creatine derivatives, namely as ergogenic aids, to increase muscular performance, as a treatment for gyrate atrophy of the choroid and retina, as a treatment for muscular dystrophy, and for cardiac functional impairment. Such ergogenic aids are typically taken by healthy athletes in order to improve muscle performance during short maximal exercise bouts. In contrast, the therapeutic preparation and methods therefor of the claimed invention are applied to individuals that

may present, or are currently presenting with symptoms of muscle disuse, rather than undergoing muscle activity, in order to retain optimal performance of skeletal muscle.

In view of the above, it is submitted that claims 9-20 are in condition for allowance. Entry of the amendments and reconsideration of the rejections are requested. Reconsideration and allowance are respectfully requested, after which the undersigned would very much appreciate a telephone call at the telephone number listed below in order to promote discussion and final resolution of the allowability of the claims.

Respectfully submitted,

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